EXHIBIT 5

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax:(513) 679-2772 Industry Information: www.fda.gov/oc/industry	07/18/2011 - 08/08/2011* FEI NUMBER 3002889431

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Douglas J. Newlin, Senior Vice President Global Engineering

FIRM NAME	STREET ADDRESS
Invacare Corporation	1 Invacare Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Elyria, OH 44035-4190	Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

A.) Specifically, procedures for corrective and preventive actions do not ensure that the actions needed to correct and prevent recurrence of nonconforming product and other quality problems are identified. For example:

1.) Risk Analysis Record # 1, dated 4/14/03, with Addendum 1, dated 1/4/11, identified grease leakage from power wheelchair motor/gearboxes as malfunctions that can cause hazards such as smoke, fire, erratic movement, and property damage. Action has not been taken to correct or prevent recurrence of grease leakage in the failure modes identified. The following returns between 12/18/10 and 8/2/11 were due to grease leakage:

a.) 71 motor/gearboxes were returned for grease leakage in the area of the motor seal, with 55 out of 71 having manufacturing dates of 2010.
b.) 89 motor/gearboxes were returned for grease leakage in the area of the gearbox cover gasket, with 55 out of 89 having manufacturing dates of 2010.
c.) 63 motor/gearboxes were returned for grease leakage in the area of the output shaft, with 55 out of 63 having manufacturing dates of 2010.

B.) The firm's procedure entitled "Corrective/Preventive Action," numbered CP14-008 with a revision date of 2/15/2011, does not ensure that all CAPAs are opened by the firm. The procedure states that "corrective and preventative actions can be initiated based on input from a variety of areas including... Internal/External quality audit results." For example, a CAPA was not initiated for 5 observations on the FDA 483 from the inspection end dated 12/17/10.

C.) FDA 483 Observations made during the FDA inspection, dated 12/17/11, were not managed through the CAPA system. The observations were instead corrected through project plans, for which there are no governing procedures.

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D.) CP14-008 "Corrective/Preventive Actions," with a revision date of 2/15/2011, does not ensure that CAPAs are opened for all "undesirable situations." For example: according to employee (b) 925 wheelchair batteries have been replaced under warranty since 12/18/2010. The warranty time period for batteries is 6 months. Since 12/17/2010, the firm has opened one CAPA associated with batteries. This CAPA, (CAR-2119) was opened due to low voltage in 5 batteries (part number 1116414), the U1 battery with handle. This CAPA does not cover all battery types used in power wheelchairs.

Repeat Observation

OBSERVATION 2

Corrective and preventive action activities and/or results have not been adequately documented.

Specifically, corrective and preventive action activities, which were performed in response to FDA-483 Inspectional Observations issued to the Sanford, FL manufacturing facility (8/18/10) and the Elyria, OH corporate facility (12/17/10) under corporate CAPA # 2011-04 were not documented. For example:

1.) There is no documented evidence to show that 132 out of 137 Risk Analysis Records of medical device malfunctions and other quality issues were reviewed to determine whether the hazards and potential risks to users and patients require further corrective or preventive actions. The June 10, 2011 corporate response letter stated that the review was performed in response to the previously issued FDA-483 Inspectional Observation #9, dated 12/17/10, to correct deficiencies related to risk analysis being incomplete.

2.) The January 1, 2011 corporate response letter to the Sanford, FL Warning Letter (FLA-11-10) item #4, which was issued for deficiencies in design validation and risk analysis, stated that all risk assessments of complaints over the past 2 years will be reviewed to determine if other design considerations should be added to the Product Design Inputs, Risk Assessment and Control Plan, Form 04013c. Out of all hazards identified in the 137 risk assessments, only 2 hazards were added to Form 04013c, such as Mechanical Design Consideration #B1, which is related to bed entrapment hazards for individuals with small body sizes, and Mechanical Design Consideration # B5, which is related to design elements that contain viscous lubricants including grease and oil.

Repeat Observation

OBSERVATION 3

Results of the design risk analysis were not adequately documented.

Specifically, risk assessments performed for product malfunctions and other quality issues, such as complaints, are not incorporated into the Product Design Inputs, Risk Assessment and Control Plans for finished power wheelchairs and bed systems. For example:

1.) Risks to user and patients of bed systems identified in Risk Analysis Record #132, such as risks of falls due to

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hazards related to the improper installation of bed rails, and risks of falls due to hazards related to the use of non-IVC mattresses and bed rails have not been added to the finished device designs, such as the Product Risk Analysis for the (b) (4) Product Specification #(b) (4) or the (b) (4) (b) (4), Product Specification # (b) (4) or the (b) (4) Series Long Term Care Bed Product Design Inputs, Risk Assessment and Control Plan, Part # CSRA.

2.) Risks to users and patients of power wheelchairs identified in Risk Analysis Record #1, such as hazards of grease leakage from power wheelchair motor/gearboxes that can cause risks to users such as smoke, fire, erratic movement and property damage have not been added to the finished power wheelchair Product Design Inputs, Risk Assessment and Control Plans: the TDX SP & TDX SR, Part #1142262; the TDX SC/TDX SPREE, Part # 1151905; the Pronto M91, Part # 1117364; and, the FDX, Part # 1163083.

Repeat Observation

OBSERVATION 4

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, Complaint handling procedures are not adequate due to:

A.) The "Complaint Handling" procedure, CP14-002, revision dated 2/7/2011, does not provide instruction on the expectations for closing complaints out in a timely manner. As of 7/19/11, there are 807 complaints which have been open for at least 6 months. When employee (b) was asked why these complaints were not closed, he stated that there was not enough resources in order to review and close all complaints received. These open complaints include both adverse event and quality complaints.

B.) The complaint handling procedure does not ensure that all complaints are evaluated and investigated in a uniform manner. Complaints are divided into two categories while they are in customer service; Adverse Events and Quality Complaints. "Complaint Handling" procedure CP14-002, revision 2/7/2011, states that an adverse event complaint is a complaint that "pertains to injury of any kind or suggest the potential for such injury." The procedure also states that these complaints are placed into this category "as a means of assigning a higher priority for review, evaluation and investigation." 16 out of 30 quality complaints reviewed had either an injury or a safety hazard associated with it. During discussion with employee (b) he agreed that 12 of the 16 quality complaints reviewed should have been raised in the system as an Adverse Event. These complaints are:

1.) PRID 1030: Created on 10/07/08. The complainant stated that the roll pin comes out and the crank comes apart on the bed.

2.) PRID 2773: Created on 6/04/09. The complainant stated that the left motor on a brand new M41 is jerking and then pulling to the left.

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3.) PRID 3583: Created on 10/07/09. The complainant stated that the dealer had issues with a couple of Personal Care Products:

- Including a bracket underneath the seat that holds the back braces in places busted within 2 weeks.
- Commode came in missing one rubber foot.
- Very difficult to open and close walker, folding mechanism and wheels seem to be bent and not roll freely.
- Locking mechanism is very difficult to open and close.

4.) PRID 3877: Created 12/08/09. Both sides of rear wheel caster bearing upper and lower have been replaced since purchased in August of 2009. Patient is under weight limit.

5.) PRID 3925: Created 12/15/2009. The front wheels of the walker angle outwards. When wheels are used and the walker is pushed the walkers legs move further apart until the walker tips over. The complainant states that this is very dangerous.

6.) PRID 4490: Created 04/08/2010. Four out of five rollators had to be returned for several reasons including:

- Two of the rollators had brakes that would not engaged.
- One of the handles went off to the side.
- A leg was completely broken in half under the seat.

7.) PRID 5778: Created 09/02/2010. The motor is leaking black liquid from drain hole on the bottom. The dealer has replaced the motor and the new one has the same drain hole.

8.) PRID 6777: Created 12/23/2010. A dealer stated that he had more than one instance where the front fame on a walker is bending at the point where the folding mechanism attaches to the front frame. It is bending on both sides, which causes the walker to collapse.

9.) PRID 7277: Created 2/21/2011. The complainant stated that he had three (3) new IRC5PO2 compressor units that were defective right out of the box.

- Compressor won't start. The unit was powered on and would not start. Complaint was confirmed.
- The unit's red light flashes then low O2 light flashes.
- The unit ran for minutes and it started whistling and getting hot. The customer's home smelt like burnt plastic.

10.) PRID 7350: Created 2/25/2011. The customer called in and stated that on this is his second 6895 mariner and that he is having trouble with his brakes. He also stated that his first mariner had issues with the brakes and they had to be replaced three (3) or more times in a twelve (12) month period. The user does not trust his chair and his caregivers are worried about it being safe.

11.) PRID 7563: Created 3/14/11. The complainant stated that the seat pan on the Solara3g had sharp edges and

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was not painted.

12.) PRID 8486: Created on 6/06/2011. The dealer stated that this is the second XP02 DC cord that gets extremely hot. The cord actually melted on the previous order.

13.) PRID 8692: Created on 6/20/2011. The 6 concentrator units alarming due to sieve bed powder leaking.

14.) PRID 8727: Created 6/22/2011. The fixed frame on a Pro Spin will not open properly. The seat rails flare into a "V" and will not align with the front capped H blocks. "The end users daughter injured her finger trying to get the chair to open and align properly."

15.) PRID 8821: Created on 06/20/2011. Dealer stated that the AC cord for the SOLO2 POC was getting so hot the end user had to use a rag to pick it up. There was also a plastic smell to the unit.

16.) PRID 8978: Created 7/12/2011. The complainant stated that the TDX-Spree chair and that this is the second chair where the caster mount is coming loose from the frame mount.

C.) Customer calls that are reported as user errors are not considered complaints and are not tracked when received. According to employee(b) (6) calls where a customer calls saying his foot pedal broke off after running his chair in to the wall are not considered customer complaints nor are they returned as warranty returns, instead she stated that the records of these calls are thrown away.

D.) 35 out of 35 calls that appear to be complaints listed in customer service call logs were not added to the complaint handling system. The following complaints are 3 examples:

1.) In employee(b) (6) call log: On Thursday, 6/30/11 at around 4:29pm a call was received from a consumer who stated that "M61 on board charger" was "not charging batteries" and that there were "no indication lights on charger." According to employee(b) (6) the complaint was not added to the complaint database.

2.) In employee(b) (6) call log: On 7/18/11, call number 8 says about a STORMTDX3 "Plugged into charge all night chair will not come on." According to employee(b) (6) the complaint was not added to the database.

3.) In employee(b) (6) call log: On an unknown date and time, a call was received saying (b) (6) nut stripped" and the "wheel was coming loose" and "leaking." According to employee(b) (6) the complaint has not been added to the complaint database.

E.) Five (5) complaints that were made on the firm's facebook.com page between 12/18/2010 and 7/27/2011 were not added to the firm's complaint database. According to employee(b) (6) here is no evidence of these complaints being entered into the complaints database. These complaints include:

1.) On June 21 (2011), a post was added to Invacare's wall asking: "What's up with your motors? I had two blow on

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me in 4 months!"

2.) On June 2 (2011), a post was added to Invacare's wall saying: "My A4 Titanium chair has once again locked up with the quick release axels making it impossible for me to remove the wheels to get my chair into the vehicle."

3.) On May 31 (2011), a post was added to Invacare's wall saying: "My Dad's Lynx3 power chair has electrical problems where is the manual nt seems it wants to turn the brakes on and stop! Never did before. Why"

4.) On April 10 (2011), a post was added to Invacare's wall saying: "My neice has the Invacare Spree GT. I have never seen a chair with so many problems. It is so big and is always in the shop."

5.) On March 6 (2011), a post was added to Invacare's wall saying: "Are Pronto 51's supposed to pitch forward like the TDX."

Repeat Observation

OBSERVATION 6

Complaint files are not adequately maintained.

Specifically, CP14-002 "Complaint Handling and Medical Device/Vigilance Reporting" with a revision date of 2/7/2011 states, "All Adverse Event complaints must be investigated." All adverse event complaint files reviewed does not contain information regarding the investigation conducted that is required. For example:

A.) Investigations completed as part of the legal processes were not maintained inside files associated with the adverse event complaint. Regulatory affairs was not aware of investigation information contained in the legal files. For example:

1.) PRID 3078: A Toxicology report and a Fire analysis was conducted as investigational activities associated with a complaint and kept in the legal file. These activities were not documented in the compliant database nor part of the hard copy complaint file.

2.) PRID 11838 (1470): An investigation was conducted by a fire expert and pictures of the chair were contained in the legal file. These activities were not documented in the compliant database nor part of the hard copy complaint file.

Repeat Observation

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OBSERVATION 6

Design input requirements were not adequately documented.

Specifically, design input requirements related to human factors and the needs of patients and users of power wheelchairs and hospital beds are not identified in Product Design Input/Output Matrixes of the medical devices. Procedure CP04-006 titled, "Design Inputs/Essential Requirements," states that the design input/essential requirements are to include hazard mitigation plans from the risk assessment. The following finished product design input requirements have not been updated to include hazards identified in risk assessments that were performed for product malfunctions and other quality issues:

A.) Three (3) out of 3 power wheelchair Product Design Input/Output Matrixes reviewed do not contain design input requirements for the identified hazards: TDX SP, Part # 1142261; TDX Spree & TDX SC, Part # 1154222; and, the M91 with Sure Step, Part # 1110624. Risk Analysis Record #1, dated 4/14/03, with Addendum dated 1/4/11, identified grease leakage from power wheelchair motor/gearboxes as hazards that can cause risks to users such as smoke, fire, erratic movement and property damage.

B.) Four (4) out of 4 bed systems reviewed do not contain design input requirements for the identified hazards: Nursing Home Beds Models IH820 DLX, IH820-3M & IHSC900 DLX, Part # 1140349; IVC Luv Beds, Part # 1128337; IVC Bariatric Bed BAR600IVC, Part # 1125303; and, IVC Homecare Bed, Part # 1117166. Risk Analysis Record #132, dated 1/10/11, identified the following hazards for Homecare and ICC bed systems:

1.) Head entrapment hazard in bed systems for individuals with small body sizes with a high severity rating of death or serious injury;

2.) Fall hazard in bed systems when entering or exiting the bed due to incorrect installation of bed rails with a medium severity rating that may cause temporary or medically reversible adverse health consequences;

3.) Fall hazard in bed systems when entering or exiting the bed due to non-Invacare (IVC) mattresses as an accessory with a severity rating of medium that may cause temporary or medically reversible adverse health consequences; and,

4.) Fall hazard in bed systems when entering or exiting the bed due to non-IVC rails as an accessory with a medium severity rating that may cause temporary or medically reversible adverse health consequences.

Repeat Observation

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OBSERVATION 7

Procedures for design output have not been adequately established.

Specifically, procedure CP04-016 titled, "Design Outputs/Device Master Record," and procedure CP04-014 titled, "Design Verification/Validation," does not ensure that design output is defined and documented in terms that allow an adequate evaluation of conformance to design input requirements. The following design output test reports on the TDX SP Product Design Input/Output Matrix, Part # 1142261, Rev I, do not show that design input requirements have been met:

1.) In section 1.5, for input requirements for Motor/Gearbox Drive Durability:

a.) Twenty (20) out of thirty seven 37 test reports were either performed on 2 pole motors, which are not used on the TDX SP, or did not apply to the current version of the design: Test Report #'s 071406TN, 100209TN.3, 120809TN.1, 120809TN.2, 071406TN.3, 111809TN.18, 021210TN.4, 021210TN.5, 071406TN.2, 111809TN.8, 012810TN.3, 021210TN.6, 021210TN.7,0817061N.5, 021210TN.3, 081706TN.2, 010510TN, 021210TN.1, 090606MG.2, AND 090606MG.3.

Repeat Observation

OBSERVATION 8

Procedures for design change have not been adequately established.

Specifically, "Change Request (CR)/Notification (CN) System" procedure CP05-006 and "Design Verification/Validation" procedure CP04-014 do not ensure that design changes are appropriately verified or validated prior to implementation.

A.) Design changes made to bed systems do not have verification or validation tests as follows:

1.) ECN # 1145004, with manufacturing effectivity date 2/14/11, created the "Bed Rail Entrapment Risk Notification Guide," Part # 1171780, in response to the risks of death and serious injury due to head entrapment hazards in bed systems for individuals with small body sizes (Risk Analysis Record # 132). ECN # 1145010, with Urgent Implementation Date 6/10/11, revised the "Bed Rail Entrapment Risk Notification Guide," to include multiple languages and add it to the Bills of Materials for shipment with bed systems, bed rails, and mattresses.

2.) ECN #1145002, with manufacturing effectivity date 5/10/11, updated the Bariatric Bed Owner's Manual, Part # 1123842, and created a new caution label to the bed regarding mis-keying crossover cables to the junction box.

B.) Design changes made to power wheelchairs are approved with failing validation test results.

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1.) ECN # 1003034, with manufacturing effectivity date 3/16/11, launched SSD motor/gearboxes on the TDX SP power wheelchair.

a.) Validation test report 030811DW, with report date 3/10/11, shows that 4 out of 6 power wheelchairs used in the validation did not conform to the RPM requirements for motors in the final audit checklist. For example: Model 3GTQSP serial # 11CE000140; Model 3GTQ3-CG serial # 11CE000621; Model TDXSPEURO23N serial # 11CE001431; TDXSPEURO23N serial # 11CE001432.

b.) Validation test report 111610DW, with report date 12/6/10, shows 3 out of 4 power wheelchairs used in the validation did not conform to requirements in the final audit checklist. Model TDXSP serial #'s 10KE004109 and 10KE004334 did not conform to RPM requirements for motors. Model TDXSP-MCG serial # 10KE004141 did not conform to the recline requirements.

Repeat Observation

OBSERVATION 9

Procedures to ensure sampling methods are adequate for their intended use have not been adequately established.

A.) Specifically, procedures for statistical techniques do not address the standard sampling plans being used for analyzing quality data; such as, "Zero Acceptance Number Sampling Plans," 5th Edition (C=0 sampling plan) and ANSI/ASQ Z1.4-2008 titled, "SAMPLING PROCEDURES AND TABLES FOR INSPECTION BY ATTRIBUTES." Procedure CP20-001 titled, "Statistical Techniques," and procedure CP20-002 titled "Trending and Analysis of Data," do not include requirements for ensuring that the aforementioned standard sampling plans being utilized are appropriate for their intended use. For example:

1.) "Zero Acceptance Number Sampling Plans" (C=0): Statistical Techniques procedure CP20-001 only includes this standard as a reference document in section 4.6, and does not address its use anywhere else in the procedure. Trending and Analysis of Data procedure CP20-002 does not mention this standard at all. Additionally, this C=0 sampling plan was inappropriately used to perform a retrospective review (AQL 1%, C=) of design control documentation deficiencies cited in PDA-483 Inspectional Observations #10, #11, and #12, issued to the corporate facility 12/7/10. The C=0 sampling plan shows that it is used for units of product (physical samples) and does not indicate that it can be used for the review of quality records. Instead of using a risk based approach for the retrospective review of the design control deficiencies related to design changes, design verification, and design outputs, the C=0 standard was used, without providing an appropriate rationale for its use.

2.) ANSI/ASQ Z1.4-2008 titled, "SAMPLING PROCEDURES AND TABLES FOR INSPECTION BY ATTRIBUTES (Z1.4 standard):" Statistical Techniques procedure CP20-001 and Trending and Analysis of Data procedure CP20-002 do not mention this standard at all, including its appropriate intended use. Additionally, the

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Z1.4 standard is shown in section 8.1.6.2 of the "Design Verification/Validation" procedure CP04-014 for determining minimum product sample size quantities used in validation testing, without showing that the standard is appropriate for its intended use.

OBSERVATION 10

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

A.) Specifically, 3 out of the 28 adverse event complaints, which were still open as of 7/18/11, and did not have an MDR reported after your firm received information which suggests a serious injury or death had occurred.

1.) PRID 7942: The complaint was received on or around 4/5/2011. The complaint information states that a consumer was sitting in his chair and when he went to move the chair forward he "fell out of it, flat on his face and broke his nose."

2.) PRID 4998: The complaint was received on or around 6/14/2010. The complainant called and stated that the chair drove off the lift. The chronology states that the consumer went to the ER and was "treated and released for minor bruises."

3.) PRID 3078: The complaint was received on or around 7/16/2009. A consumer died when he fell asleep on an Invacare bed with a lit cigarette.

B.) Specifically, 1 out of the 13 MDRs reviewed was filed with the FDA after the 30 day requirement.

1.) PRID 8648: According to the Consumer Incident Reporting Form, the complaint was received on 6/3/2011. According to block entitled "Date of This Report," the report was filed on 07/07/2011. The report was filed at 34 days which is 4 days over the 30. The MDR was filed due to the fact that the wheelchair was causing the consumer to bruise. The consumer had to go to the doctor who put medication on his arm.

Repeat Observation

OBSERVATION 11

The written MDR Procedure does not include an internal system which provides for the timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements.

Specifically, the firm's MDR handling procedures CP14-002, entitled "Complaint Handling and Medical Device/Vigilance Reporting," with a revision date of 2/7/2011, and RAWI 14-003 entitled Adverse Event Complaint File Handling and MDR Reporting," with a revision date of 2/14/2011 do not describe an internal system that provides for timely and effective

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772 Industry Information: www.fda.gov/oc/industry	07/18/2011 - 08/08/2011* FEI NUMBER 3002889431

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Douglas J. Newlin, Senior Vice President Global Engineering

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identification, communication and evaluation of events that could meet MDR requirements.

A.) Investigation activities to be conducted for MDR events are not described.

B.) The procedures do not establish when supplemental information received for an MDR will be communicated with the FDA.

C.) Documentation and recordkeeping requirements for information that was evaluated in MDR determinations, as well as documents maintained in the MDR files are not described.

D.) In Section 7.1 under "Notes," number 6 states that "If a malfunction occurs in a device not manufactured by Invacare Corporation that is likely to cause a death or serious injury and the manufacturer of the device is unknown, the event must be reported to the FDA." The procedure should not be limited to only malfunctions.

OBSERVATION 12

The importer failed to submit a report to the manufacturer on FDA Form 3500A within 30 days concerning information that one of the devices marketed by the importer has malfunctioned and that such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, copies of the 3500A forms were not sent to the manufacturer for 2 out of 11 MDRs reviewed for those products imported and/or distributed by your firm. These MDRs are:

A.) PRID8929: The consumer was using a rollator when the fork on the front caster broke, causing the rollator to collapse and making the customer fall. The MDR was filed on 7/14/11. A letter was sent to the manufacturer on August 01, 2011 during the FDA inspection.

B.) PRID 8367: The consumer was using the shower chair when the leg folded, which caused the consumer to fall to the floor. The MDR was filed on 6/20/11. A letter was sent to the manufacturer on August 02, 2011, during the FDA inspection.

OBSERVATION 13

Personnel do not have the necessary training to perform their jobs.

Specifically, Customer Service employees are not being trained. According to the training presentation entitled "Customer Service Training Complaint Handling", complaints that come in as "User errors: "I fell on the walker", "I drove into the wall" (No product defect)" are not being reported as adverse event complaints.

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct.
Observation 7:	Promised to correct.	Observation 8:	Promised to correct.
Observation 9:	Under consideration.	Observation 10:	Promised to correct.
Observation 11:	Promised to correct.	Observation 12:	Promised to correct.
Observation 13:	Promised to correct.		

* DATES OF INSPECTION:
07/18/2011(Mon), 07/19/2011(Tue), 07/20/2011(Wed), 07/21/2011(Thu), 07/22/2011(Fri), 07/25/2011(Mon), 07/26/2011(Tue), 07/27/2011(Wed), 07/28/2011(Thu), 07/29/2011(Fri), 08/01/2011(Mon), 08/02/2011(Tue), 08/03/2011(Wed), 08/04/2011(Thu), 08/08/2011(Mon)

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TO: Douglas J. Newlin, Senior Vice President Global Engineering

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Elyria, OH 44035-6248	Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically,

A review of the validation activities pertaining to the electronic (b) (4) (number 05117) crimping machine show that your firm did not validate a range of process variables used in the crimping operation. Crimping is the process of connecting various combinations of wire gauges/terminals in order to manufacture electronic assemblies.

The critical variables settings on the machine for a proper crimp include "conductor reference" aka wire crimp strength and an "insulation crimp" setting which forms the strain relief around the wire. Your firm only performed validation activities on single settings for crimp strength and insulation crimp even though the settings on this machine are routinely changed (but not documented) by the set-up operator.

Additionally, it was found that five (5) out of nine (9) (56%) work instructions (manufacturing detail sheets) for the crimping operation on the (b) (4) 05117 machine do not match the settings used during the validation studies for parts currently being used in production. Furthermore, three (3) of the work instructions which have been in use since December, 2005, require a wire crimp setting of "8" which is not possible as the range of settings on the machine is 1-6. These work instructions are to be used during set-up for each run.

On 7/19/11, the (b) (4) 05117 machine was observed with the following settings wire crimp strength 5.5 and insulation crimp of 5.0. These settings do not match any of the terminal wire combinations used during validation.

The firm used two pieces from each wire/terminal combination to perform pull testing for validation without having a statistical rational for only performing two (2) pull tests.

Also, your firm requires that "special processes" (processes which cannot be 100% verified) are required to be re-validated annually per your "Process Validation/Equipment Qualification" (CP09-001) and your "Process Validation" (EL09-104)

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procedure. Two (2) of the twenty one (21) processes are listed below.

1.) (b) (4) welding - last validated 3/23/06

2.) (b) (4) welding - last validated 8/4/08

Repeat Observation

OBSERVATION 2

Process validation activities and results have not been adequately documented and adequately approved.

Specifically, your firm performed process validation on the (b) (4) flatbed laser cutting device which was approved for use on 5/24/2011. Flatbed laser cutting is used to manufacture a wide variety of parts including parts for power and manual wheelchairs. As part of your operational qualification (OQ) of the machine, you performed "Production Part Inspection Report" (PPAP) for each of the most challenging materials (steel/aluminum), material thickness variations and product configurations which you identified. According to the PPAP procedure "Production Part Approval Process" (EL04-111), 5 separate pieces are to be inspected as part of this validation. For the flat cut pieces, only 1 of the 5 cut pieces was actually measured providing objective evidence of meeting specifications. The other 4 pieces were visually compared to the original cut piece (which may not have been cut to the nominal specifications) which does not provide objective evidence of meeting specifications. The tolerance for the majority of the measurements is (b) (4) inches. Also, the requirement of testing a minimum of 5 pieces is not based on any type of statistical rationale or sampling plan.

Also, another horizontal laser known as the (b) (4) flatbed laser cutting machine currently being used in production was last validated/qualified on 12/15/2003. During this validation, the worst case scenarios of material thickness, material types and different configurations of parts were not considered during the validation.

Parts which are manufactured on these machines are subject to first piece/last piece inspections checks for overall length, width material thickness and edge cut quality. The remaining pieces are not 100% verified as meeting specification but must meet functionality such as part to part matching during production.

Also, your firm identified the following CNC machines as not requiring validations as you maintain that the parts manufactured on theses CNC machines are 100% verified during a subsequent operations.

- (b) (4) vertical milling center machines
- (b) (4) vertical milling center machines
- (b) (4) upholstery cutter
- (b) (4) tube laser cutters

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- (b) (4) press brake

The parts manufactured on these machines are not being 100% verified to meeting specifications but rather are subject to first/last piece inspections and subsequent functionality tests which may not detect whether the part(s) are within specification.

Repeat Observation

OBSERVATION 3

Procedures for corrective and preventive action have not been adequately established.

Specifically,

A.) According to your "Internal Corrective/Preventive Action" procedure (EL14-100), 7/24/2008, nonconformance data from nonconforming material tags, rework tags and scrap data are among the quality data sources which may result in corrective/preventive actions. These procedures were last revised 3/4/2011 and continue to list quality data sources stemming from non-conforming products. Your firm has not performed analyses or data reviews such as trending for identified issues for potential corrective actions.

1.) From January 2009-July 2010 there were a total of 445 "REPAIR or USE AS IS" non-conforming tags identified during the previous FDA inspection ending 12/17/10). To date these records have not been analyzed or trended for potential corrective action by your firm. This practice of not analyzing or conducting data reviews for these "REPAIR or USE AS IS " tags (which later became "major rework" tags) for potential corrective actions continued through July 12, 2011 the time which you implemented your latest revision of procedures for controlling nonconforming product entitled "Quality Hold, Reprocessing, Rework and Nonconforming" (EL13-101, 6/7/11 revision with 7/12/11 implementation). Your firm estimates there are an additional 116 tags covering the timeframe from July 2010 though July 12, 2011 which also have not been analyzed or subject to data review(s).

2.) Your firm estimates there are 2900 "Rework" tags from June 1, 2010 through February 2011 which have not been analyzed or subject to data review(s) such as trending for potential corrective actions by your firm.

Your firm approved a revision of SOP "Quality Hold, Reprocessing, Rework and Nonconforming" (EL13-101) on 1/24/11(implemented on 3/17/2011) which addressed the monthly review and trending of re-processed and reworked product. A review of these trending reports from March 2011-June 2011 show that no corrective actions have been taken on any items. Your criteria for implementing corrective actions in your "Internal Corrective/Preventive Action" procedure (EL14-100, revised 2/1/11 implemented 3/4/2011) are in part based on risk, impact classification (critical, major and minor) and frequency. There is no documentation of risk or impact associated with these trending reports. Potential risk information which may be assessed on the quality hold tag is not transferred to the trending reports. These trending are typically

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what is used to generate corrective/preventive actions.

3.) From June-July 2010 there were 509 "rework by reprocessing tags" identified during the previous FDA inspection ending 12/17/10) which were dispositioned by employees who were not on the MRB list. It was found that 43 of the 509 rework operations were not on the approved reprocessing/rework list. Your firm has not reviewed these records to determine the impact of the reworks on the product or evaluated them for potential corrective actions. Additionally, from July 2010 through 3/17/11 (the date of implantation of SOP EL 13-101) your firm has not reviewed the additional "rework by reprocessing tags" (estimated by the firm to be 1744 tags) to determine whether or not non MRB members were approving reprocessing operations which were not on the approved list and subsequent impact on the product.

B.) Elyria Operations System Procedures EL04-100 "Internal Corrective/Preventive Action" with an issue date of Mar 04 2011 and EL06-101 "Supplier Corrective Action" with an issue date of MAR 02 2011 do not ensure that the scheduled monthly reviews on the Corrective Actions and Supplier Corrective Actions are completed.

22 out of 24 CARs reviewed were past the review date assigned on the Action Response Worksheets. Examples of these CARS include:

1.) CAR-2073: The corrective action was initiated to document the root cause for paintline log entries not being kept in spec. Under the review section on the CAPA it lists the "Next Review Date:" as 01-Apr-2011. According to the firm there have been no updates in the system.

2.) CAR-2075: The corrective action was initiated due to the high noises made by the motors. The specifications state that the motor noise should not be higher than 54 DB, and the motors are running as high as 58 DB. According to the "Next review Date" should be 24-Jun-2011. The next review was supposed to occur by 24-Jun-2011 and there is no documentation that any further action has occurred. According to the firm there have been no updates in the system.

3.) CAR-2080: The corrective action was initiated due to chemical maintenance not completing required tasks. According to the "Review" section of the action detail, the next review date was set for 21-Apr-2011. According to the firm there have been no updates in the system.

Repeat Observation

OBSERVATION 4

Procedures for rework of nonconforming product have not been adequately established.

Specifically,

Your procedures for controlling nonconforming product entitled "Quality Hold, Reprocess, Rework and Nonconforming

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material "(EL13-101) implemented on July 12th, 2011, do no require that non-serialized reworked product is documented in the device history record for in process nonconforming products.

Additionally, in process materials which are reprocessed at repair stations are not being captured in the device history records. These repairs typically require disassembly and re-assembly of parts and components which may add additional risks to the finished device.

Additionally, your procedures define reprocessing as reintroducing product into an existing (validated) process. This is not is not accurate as most manufacturing processes performed at your firm such as drilling, bending, tightening, hand assembly and piercing are not "validated" processes.

Repeat Observation

OBSERVATION 5

Products that do not conform to specifications are not adequately controlled.

Specifically, the firm implemented procedure "Quality Hold, Reprocessing, Rework and Nonconforming Material" procedure (EL13-101) on July 12th, 2011 which describes how to manage and control reworks, reprocessing and nonconforming material identified during production.

An inspection of the manufacturing area on 7/21-22/11 found the following:

- 13 different power wheelchair parts (brackets and tubes) which appeared to be scrap were found in a "dispatch" bin for pivot tubes without identification as to the status or disposition of the parts. As such, these parts were not being treated or used as part of my quality data analysis.

- 2 out of 2 (100%) parts found in a designated nonconforming parts bin were tagged with a red non-conforming tag with no information regarding the part number or description of the non-conformance documented on the tag. These red tags (which are not currently used by your firm) are not described in the current procedure and were later found to be used by a supplier who was returning parts. The current procedure states that quality hold tags are to be used to identify non-conforming products.

- On 7/21/11, 7 out of 8 (88%) parts found in a scrap bin (footrest pieces for power wheelchairs) where not captured on the scrap disposition report as required by the "Scrap Disposition Report" procedure (T-00-13-02) implemented on July 1, 2011. Scrap rates and trending information is created by using data from these disposition reports. On 7/22/11 a scrap disposition report was provided that was dated 7/22/11. This report, which was not completed at the time of that the parts were scrapped, only accounts for 3 of the 7 scrapped footrest pieces. Also, there is no evidence that the operator (ID# 271) was trained on the current scrap disposition report procedure.

- 10 out of 30 parts (33%) used on power wheelchairs were found in a nonconforming parts bin for fabrication issues were not identified as described in "Quality Hold, Reprocessing, Rework and Nonconforming Material" procedures (EL13-101). According to procedures "the area of concern is identified on the component". This was not

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done for the 10 parts as there were no identifying marks.

OBSERVATION 6

There is no documentation of monitoring and control methods and data and the individual performing the process for a validated process.

Specifically,

Your firm currently uses (b) (4) pneumatic crimping machines and (b) (4) electronic crimping machines in order to manufacture components and sub-assemblies for a variety of power wheel chairs/accessories to include the TDX series, M series and Storm series.

Your firm does not record the machine settings/variables or the individual running the process for any of these machines during production.

OBSERVATION 7

Schedules for the adjustment, cleaning, and other maintenance of equipment have not been adequately established.

Specifically, a review of the weekly maintenance records for (b) (4) flatbed laser cutting machine showed that 20 out of 45 (44%) records were incomplete per "Flat Sheet Laser Machine Inspection Weekly Maintenance and Water Change Procedure" (T-04-09-12).

Also, a review of 316 daily maintenance records (which includes (b) (4) steps) for the (b) (4) flatbed laser cutting machine showed:

24 records did not record the laser output.

Also, failures which were identified in the daily checklist do not show documentation of how the failure was corrected. Your firm does not have a mechanism by which to document corrective actions to failed maintenance items and subsequently show the corrective action was effective for weekly or daily maintenance for the flat laser.

The (b) (4) flatbed laser cutting has been in service since late June, 2011. To date there are no daily or weekly maintence sheets for this machine, which is used for similar operations as the (b) (4) flatbed lasers. Additionally, procedures describing the daily/weekly activities for this machine have not yet been established.

Repeat Observation

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OBSERVATION 8

Procedures for the acceptance of in-process product have not been adequately established.

Specifically, on 7/25/11, three (3) separate workstations for the testing of battery harness, locking cylinder, and cable battery assembly, were found in-process with green QC approval stickers which were completed, prior to a testing operation being conducted. There were no employees present at the work stations where these stickers were found. These stickers are used to show that a part or component has been tested and has passed the inspection. The firm does not have in-process acceptance procedures to describe the control of these QC stickers. Two of the three workstations have associated work instructions which show the step where the QC stickers are applied.

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Observation 7:	Promised to correct.	Observation 8:	Promised to correct.

* DATES OF INSPECTION:
07/18/2011(Mon), 07/19/2011(Tue), 07/20/2011(Wed), 07/21/2011(Thu), 07/22/2011(Fri), 07/25/2011(Mon), 07/26/2011(Tue), 07/27/2011(Wed), 07/28/2011(Thu), 07/29/2011(Fri), 08/01/2011(Mon), 08/02/2011(Tue), 08/03/2011(Wed), 08/04/2011(Thu), 08/08/2011(Mon)

	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Rosanna M. Vaccaro, Investigator Benjamin J. Dastoli, Investigator Rebecca Clark, Investigator	00/08/2011